

REMARKS

The amendment to the specification does not add new matter. Rather, it complies with the request of the Patent Office to update the status of the pending applications.

The amendments to the claims also do not add new matter. Many of the amendments comply with the request of the Patent Office to change “comprising” to “further comprising.” Claims 12, 13 and 69, which have been amended to recite the Markush group “selected from the group consisting of a bone morphogenic protein (BMP), an antibiotic, a growth factor, a nucleic acid and a peptide,” are supported throughout the specification, including at page 6, lines 23-24. The amendment to claim 71 is supported by FIG. 8. Claim 72, which has been amended to recite an implant “having a superior vertebra engaging surface and an inferior vertebrae engaging surface, said surfaces having ridges or teeth machined therein to assist in retention of the implant when placed between the vertebrae,” is supported by FIG. 8 and the written disclosure at page 15, lines 21-26.”

For all these reasons, the amendments to the specification and claims do not add new matter.

Applicants also submit substitute drawings for FIGS 1 (now labeled as FIG. 1) and for informal FIGs. 28-34. It is requested that these substitute figures, which do not add new matter, be substituted for the original filed FIGS 1 and the less formal FIGs 28-34.

Bases for Objection/Rejection

The Patent Office rejected claims 14, 70, 71, 72, 74 and 78 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite.

The Patent Office objected to claim 77 for failing to limit a previous claim.

Claims 40, 43-44 and 49 are provisionally rejected for obviousness-type double patenting over claim 60 of copending Application SN 11/073,202.

Claims 62 and 63 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by EP 0517030 (Siebels).

Claims 11-12, 39, 43-44 and 58 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by EP 0517030 (Siebels) or in the alternative under 35 U.S.C. § 103(a) for being obvious over Siebels alone.

Claims 14, 30-36, 40-42, 49-50, 53-56, 60-61, 63-66, 68-69, 71-72, 74-80 and 89 are rejected under 35 U.S.C. §103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates).

Claim 13 is rejected under 35 U.S.C. §103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 4,828,563 (Mueller-Lierheim).

Claims 81-83 and 88 are rejected under 35 U.S.C. §103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of Albee or U.S. Pat. 5,192,237 (Brantigan) or U.S. Pat. 5,861,041 (Tienboon).

Claims 85-87 are rejected under 35 U.S.C. §103(a) for allegedly being unpatentable over EP 0517030 (Siebels) and U.S. Pat. 5,989,289 (Coates) as applied to claim 14, and further in view of Albee, U.S. Pat. 5,192,237 (Brantigan) or U.S. Pat. 5,861,041 (Tienboon).

The Applicants will address each of these bases for objection/rejection in Sections I-IX, respectively.

I. 35 U.S.C. § 112, Second Paragraph

The Patent Office rejected claims 14 (now cancelled), 70 (withdrawn), 71, 72, 74 and 78 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. According to the Patent Office, the transitional terms “comprising” are confusing because the implant components have been set forth in claim 11. The Patent Office suggests using “further comprising” instead. In response, the Applicants have amended the relevant pending claims by inserting the word “further” in front of the first occurrence of the word “comprising.” Accordingly, this basis for rejection has been rendered moot.

II. Objection to Claim 77

The Patent Office objected to claim 77 for failing to limit a previous claim. Claim 77 has been amended to include a structural limitation as to size. Accordingly, this basis for rejection has been rendered moot.

III. Obviousness-Type Double Patenting

Claims 40, 43-44 and 49 are provisionally rejected for obviousness-type double patenting over claim 60 of copending Application SN 11/073,202. Applicants will address this basis for provisional rejection at such time as claims are allowed in the present application or in copending Application SN 11/073,202.

IV. 35 U.S.C. § 102(b) over EP 0517030 (Siebels)

Claims 62 and 63 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by EP 0517030 (Siebels). However, claims 62 and 63 have been cancelled by amendment herein. Accordingly, this basis for rejection has been rendered moot.

V. 35 U.S.C. § 102(b)/103(a) over EP 0517030 (Siebels)

Claims 11-12, 39, 43-44 and 58 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by EP 0517030 (Siebels) or in the alternative under 35 U.S.C. § 103(a) for being obvious over Siebels alone. Claims 43-44 and 58 have been cancelled by amendment herein. Accordingly, only claims 11-12 and 39 remain subject to this basis for rejection.

Siebels discloses a molded assembled implantable device composed of fiber reinforced polymeric resin. In contrast, claim 11 and its two dependents (claims 12 and 39) each recite as elements, “machined segments of allograft bone.” These elements are neither taught nor suggested in Siebels. Accordingly, claims 11, 12 and 39 would not be anticipated by or obvious over the disclosure in Siebels.

VI. 35 U.S.C. § 103(a) over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates)

Claims 14, 30-36, 40-42, 49-50, 53-56, 60-61, 63-66, 68-69, 71-72, 74-80 and 89 are rejected under 35 U.S.C. §103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates). Claims 14, 36, 40-42, 49-50, 53-55, 63, 65-66 and 89 have been cancelled by amendment herein. Thus, only claims 30-35, 56, 60-61, 64, 68-69, 71-72 and 74-80 remain pending and subject to this basis for rejection.

According to the Patent Office, “Siebels discloses an assembled bone implant made by assembling separate **bone** implant pieces together by aligning bores of adjacent pieces” and “Siebels introduces pins into the aligned **bones** to hold the implant pieces together.” [Official Action at page 7, citing Siebels translation at Figs 1 and 2, page 8 and page 9; emphasis added in bold.] Notwithstanding the Patent Office’s use of the word “bone” to describe the disclosure in Siebels, the Patent Office admits that **“Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for reinforced plastic.”** [Official Action at page 8; emphasis added in bold.] In fact, Siebels only mentions plastic (e.g., “prefabricated solid or hollow strand [page 3, line 7]”) and neither cited Figs 1 or 2, nor pages 8 nor 9 of Siebel ever mention the word “bone” or bone pieces. If the Patent Office sees the word “bone” in its cited portions of Siebel, then it is respectfully requested that it point out the exact location or withdraw its unsupported statements such as Siebels “introduces pins into the aligned bones.”

To make up for the actual deficiency in Siebels, which is limited to “prefabricated solid or hollow strand [page 3, line 7],” the Patent Office further cites to Coates. According to the Patent Office, Coates “teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo.” [Official Action at page 8. citing to Coates at the Abstract, col. 2, line 33 to col. 3, line 45, col. 7, lines 18-43, and col. 11, lines 42-61.] The Patent Office then concludes that it would have been obvious to make the disk and pins out of cortical bone for the same reason that Coates teaches doing the same.” [Official Action at page 8.] Applicants respectfully disagree. Not only does the Siebels teach away from the cited combination with cortical bone, but also the prior art as a whole (including Brantigan) fails to disclose

that cortical bone has “superior properties” (plural) over fiber- or carbon-reinforced plastic as alleged.

A. The Combination of Siebels and Coates Fails to Provide a “Suggestion to Combine” or a Reasonable Expectation of Success

In order for an invention to be obvious, “Both the suggestion and the expectation of success must be founded in the prior art, not in applicant’s disclosure.” *Amgen v. Chugai*, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); emphasis added in bold. In the present case, Siebels discloses that it was an object of their invention to make an implant that can “easily be manufactured for a multiplicity of overall dimensions:”

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also **easily be manufactured for a multiplicity of overall dimensions**, forms the basis of the [proposed] invention.

In accordance with the invention, the set objective is achieved with the help of the features, cited in claim 1.

[English Translation of Siebels at page 2, line 20 to page 3, line 1; emphasis added in bold.]

To achieve the “ease” of manufacturing, Siebels relies upon cutting discs out of “prefabricated solid or hollow strand.” [English Translation of Siebels at page 3, line 7.] Specifically, Siebels discloses that this mode of manufacturing, comprising cutting appropriately sized strands made of “fiber reinforced plastic” provides for “manufacturing” in a “extraordinarily easy way”:

The disk-shaped implant is preferably made of fiber-reinforced plastic [FRP]. In accordance with a preferred embodiment of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are

characterized in that they can be manufactured in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity and strength** to the implant.

[English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

Thus, the heart of Siebel's invention is a prefabricated template that can be cut into directly useable slices to produce an implant "in an **extraordinarily easy way**." By use of the adjective "extraordinary," Siebels meant to convey that the disclosed process of manufacturing plastic implants was not just "easy" but "**extraordinarily easy**."

In addition, the above quote from Siebels teaches that "**fiber orientation**" is important because it "imparts an **optimal rigidity**." The word "**optimal**" is a superlative and means "most favorable or desirable; best; optimum." [Exhibit B: Webster's New World Dictionary, Second College Edition, Ed. Guralnik, Prentice Hall Press, 1986 at page 999; emphasis added in bold.] Thus, **fiber orientation** is a necessary element in the material used by Siebels to "impart **optimal rigidity**."

In contrast to the "extraordinarily easy" method of manufacturing disclosed in Siebels (that provides for an implant having "optimal rigidity"), Coates discloses that "developing an implant having the biomechanical properties of metal and the **biological properties of bone** without the **disadvantages of either** has been **extremely difficult or impossible**." [Coates at col. 3, lines 35-39.] By this statement, Coates teaches that as of its filing date (October 1995), cortical bone was not a "traditional orthopedic implant material" for spinal implants. Rather, it was considered "**extremely difficult or impossible**" to provide an implant that had the benefits of both bone and metal without their undesired properties. The words "extremely difficult or impossible" are **superlatives** related to difficulty or impossibility. Given this "**extremely difficult or impossible**" setting of developing an implant from cortical bone, one skilled in the art would not have been motivated to substitute cortical bone of Coates for the "**extraordinarily easy**" to use preformed plastic of Siebels. Moreover, given the art recognized "**extreme difficulty or impossibility**" of developing a **single piece** implant from cortical bone as disclosed in Coates, one skilled in the art would have been even **less motivated** to build an implant assembled from **little pieces of cortical bone** held together with pins, and given the stated

“extreme difficulty” there would not have been a reasonable expectation of success that the Applicants’ would have been able to make implants assembled from little pieces of cortical bone. See *Amgen v. Chugai*, 18 USPQ2d at 1022. For these reasons, claims 30-35, 56, 60-61, 64, 68-69, 71-72 and 74-80 would not have been obvious under 35 U.S.C. § 103(a) over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates).

B. The Cited Art Teaches Away from Combining Siebel with Coates

“A prior art reference may be considered to teach away when ‘a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction **divergent from the path taken by the applicant.**” See *Monarch Knitting v. Sulzer*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998); emphasis added in bold. In the present case, one skilled in the art, upon reading Siebels “extraordinarily easy” method for producing an implant having “optimal rigidity” due to the fiber orientation would have been led in a direction **divergent** from the “extremely difficult or impossible” path of making even a single piece implant from cortical bone as disclosed in Coates. Because Siebels led in a divergent direction from the path taken in Coates, Siebels taught away from Coates. As a matter of law, it is “error to find obviousness where references ‘diverge from and teach away from the invention at hand.’” *In re Fine*, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988) citing *Gore v. Garlock*, 220 USPQ 303, 311 (Fed. Cir. 1983). For this reason also, the combination of Siebels and Coates would have failed to make a prima facie case of obviousness at the time the Applicants’ invention was filed.

C. The Prior Art As A Whole Fails to Teach a Plurality of Advantages for the Cortical Bone Implant of Coates

The Patent Office contends that “Coates teaches that it was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties.” [Official Action at page 2.] The Applicants respectfully disagree. One of the properties to be considered was the ease of manufacturing the implant.

Therefore, the objective to develop an implant of the kind mentioned at the outset, which can rapidly be implanted and which - from the standpoint of manufacturing engineering - can also **easily be manufactured** for a **multiplicity of overall dimensions**, forms the basis of the [proposed] invention.

In accordance with the invention, the set objective is achieved with the help of the features, cited in claim 1.

[English Translation of Siebels at page 2, line 20 to page 3, line 1; emphasis added in bold.]

Siebels discloses that his implants can be made in an “extraordinarily easy way” and provide “optimum rigidity” and “strength” to the implant:

Implants of this kind are characterized in that they can be manufactured in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity and strength** to the implant.

[English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

In contrast, Coates teaches that “developing an implant having the biomechanical properties of metal and the **biological properties of bone** without the **disadvantages of either** has been **extremely difficult or impossible**.” [Coates at col. 3, lines 35-39.] Thus, the material used in the device of Siebels has at least one major advantage not found in the implant of Coates.

The fiber-reinforced plastic and the carbon-reinforced plastic of Siebels is the same fiber reinforced plastic and the carbon reinforced plastic disclosed in U.S. Pat. (Brantigan) which is already of record. When Coates addressed disadvantages, they were in relation to “metal” implants, not the fiber-reinforced implants of Siebels or Brantigan:

developing an implant having the biomechanical properties of **metal** and the biological properties of bone without the **disadvantages of either** has been **extremely difficult or impossible**.

[Coates at col. 3, lines 35-39.]

However, Siebels' implants are not limited to metals. Siebels also teaches that its **preferred embodiment** is not a metal either, but rather is a fiber (e.g., graphite) reinforced plastic (as on the stealth bomber), which does not have the disadvantages associated with metal such as stress-shielding, or radio-opaqueness:

The disk-shaped implant is **preferably made of fiber-reinforced plastic [FRP]**. In accordance with a **preferred embodiment** of the invention, in order to produce a single-piece implant, the disk is cut out of a hollow strand, which consists of a multiple number of braiding layers [plaiting layers]. The braiding layers, are wound up one after another on a correspondingly shaped mandrel [arbor], preferably on a mandrel, having rectangular cross-section and rounded corners, directly in a braiding machine. The disks are cut off with the desired height, which can vary over the disk. Implants of this kind are characterized in that they can be manufactured in an **extraordinarily easy way**, in which the **fiber orientation** equally **imparts an optimal rigidity and strength** to the implant.

[English Translation of Siebels at page 3, line 22 to page 4, line 9; emphasis added in bold.]

[See also Brantigan at col. 3, lines 9-12 ("The **implants are preferably made of radiolucent material such as carbon fiber reinforced polymers. . .**").] Coates does not address or overcome the advantages associated with fiber reinforced plastic, so as to motivate one skilled in the art to disregard the advantages associated with Siebels' ease of construction and stated advantages relative to bone which required complex machining and which was totally untested in stacked formation. In fact, Siebels states that this preferred embodiment imparts "**optimal rigidity.**" Brantigan also teaches that the fiber- and carbon-reinforced plastic polymers are radiolucent, unlike metal. Coates never addressed this embodiment in Siebels, which Siebels also disclosed was "preferred" over metal. Thus, Coates does not disclose that cortical bone has "superior properties" over the fiber-reinforced polymers of Coates (or Brantigan).

For this reason also, the combination of Siebels over Coates would have failed to render obvious claims 30-35, 56, 60-61, 64, 68-69, 71-72 and 74-80 at the time that the Applicants' invention was made.

VII. 35 U.S.C. § 103(a) over EP 0517030 (Siebels) in view of U.S. Pat. 4,828,563 (Mueller-Lierheim)

Claim 13 is rejected under 35 U.S.C. §103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 4,828,563 (Mueller-Lierheim). Claim 13 is directed to an assembled implant made from machined allograft bone that is held together with machined allograft bone pins and wherein a segment of allograft bone or a bone pin is soaked, infused, or impregnated with a “material selected from the group consisting of a bone morphogenic protein (BMP), an antibiotic, a growth factor, a nucleic acid, a peptide, and a combination thereof.” According to the Patent Office, Siebels is cited for the same reasons as set forth above relative to claim 11. Mueller-Lierheim (Mueller) is cited for teaching that “it was known to coat similar implants in the art with growth factors.” [Official Action at page 8, citing the Abstract of Mueller.] However, Mueller implants were different and not similar. According to Mueller “implant” was defined as prostheses and artificial organs:

In this specification, the term **implant** is used to denote **not only prostheses but also artificial organs**, for example artificial kidneys, vessels, skin substitute, artificial eye lenses, so-called intraocular lenses, dental prostheses and also contact lenses.

[Mueller at col. 1, lines 9-14; emphasis added in bold.]

Separately, Mueller’s method of attachment, as disclosed in the Abstract relied upon by the PTO, discloses that the body of the implant is coated with a polymer (unlike the Applicants’ invention) and that the polymer has “bonding- active groups” which “covalently” bind the unidentified “growth factors.” In contrast, in the Applicants’ invention of claim 13, there is no polymer coating and the bone morphogenic protein or growth factor of claim 13 is not chemically affixed by active bonding groups that react with and covalently bond the growth factor to a polymer. Rather than chemical bonding, claim 13 recites that the bone pin or bone segment are physically “soaked, infused or impregnated” with the growth factor. For these reasons, claim 13 would not have been obvious over Siebels in view of Mueller.

VIII. 35 U.S.C. § 103(a) over EP 0517030 (Siebels) in view of Albee or U.S. Pat. 5,192,237 (Brantigan) or U.S. Pat. 5,861,041 (Tienboon)

Claims 81-83 and 88 are rejected under 35 U.S.C. §103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of Albee or U.S. Pat. 5,192,237 (Brantigan) or U.S. Pat. 5,861,041 (Tienboon). Claims 81-83 and 88 have been cancelled by amendment herein. Accordingly, this basis for rejection has been rendered moot.

IX. 35 U.S.C. § 103(a) over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates) and Albee or U.S. Pat. 5,192,237 (Brantigan) or U.S. Pat. 5,861,041 (Tienboon)

Claims 85-87 are rejected under 35 U.S.C. §103(a) for allegedly being unpatentable over EP 0517030 (Siebels) and U.S. Pat. 5,989,289 (Coates) as applied to claim 14, and further in view of Albee, U.S. Pat. 5,192,237 (Brantigan) or U.S. Pat. 5,861,041 (Tienboon). Claims 85-87 have been cancelled by amendment herein. Accordingly, this basis for rejection has been rendered moot.

SUMMARY

Claims 11-14, 30-44, 48-56, 60-83 and 85-89 were pending. Claims 1-10, 14-29, 34, 36-38, 40-55, 57-59, 62-63, 65-66, 70, 73, and 81-101 have been cancelled. Only claims 11-13, 30-33, 35, 39, 56, 60-61, 64, 67-69, 71-72 and 74-80 remain pending.

The rejection of claims 14, 70, 71, 72, 74 and 78 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite, has been rendered moot by the amendments herein.

The objection to claim 77 has been rendered moot by the amendment herein.

The provisional rejection of claims 40, 43-44 and 49 for obviousness-type double patenting over claim 60 of copending Application SN 11/073,202 will be addressed at such time as claims are allowed.

The rejection of claims 62 and 63 under 35 U.S.C. § 102(b) for allegedly being anticipated by EP 0517030 (Siebels) has been rendered moot by the cancellation of these claims.

The rejection of claims 11-12, 39, 43-44 and 58 under 35 U.S.C. § 102(b) for allegedly being anticipated by EP 0517030 (Siebels) or in the alternative under 35 U.S.C. § 103(a) for being obvious over Siebels alone has been rebutted in part by the arguments herein and rendered moot in part by the cancellation of certain of the claims.

The rejection of claims 14, 30-36, 40-42, 4—50, 53-56, 60-61, 63-66, 68-69, 71-72, 74-80 and 89 under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 5,989,289 (Coates) has been rebutted in part by the arguments herein and rendered moot in part by the cancellation of certain of the claims.

The rejection of claim 13 under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of U.S. Pat. 4,828,563 (Mueller-Lierheim) has been rebutted by the arguments herein.

The rejection of claims 81-83 and 88 under 35 U.S.C. § 103(a) for allegedly being unpatentable over EP 0517030 (Siebels) in view of Albee or U.S. Pat. 5,192,237 (Brantigan) or U.S. Pat. 5,861,041 (Tienboon) has been rendered moot by the cancellation of those claims.

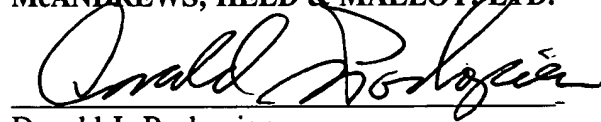
The rejection of claims 85-87 under 35 U.S.C. §103(a) for allegedly being unpatentable over EP 0517030 (Siebels) and U.S. Pat. 5,989,289 (Coates) as applied to claim 14, and further in view of Albee, U.S. Pat. 5,192,237 (Brantigan) or U.S. Pat. 5,861,041 (Tienboon) has been rendered moot by the cancellation of those claims.

Accordingly, claims 11-13, 30-33, 35, 39, 56, 60-61, 64, 67-69, 71-72 and 74-80 are in condition for allowance. Their allowance is respectfully requested.

Respectfully submitted,

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